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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Implex Hedrocel® Revision Cup

Submitter Name:	Implex Corp.
Submitter Address:	80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	John Schalago or Robert Poggie
Phone Number:	(201) 818-1800
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Date Prepared:	May 10, 2000
Device Trade Name:	Hedrocel® Revision Cup
Device Common Name:	Acetabular Reconstructive Cage
Classification Number and Name:	21 CFR § 888.3350

Substantial Equivalence: **The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.**

Device Description: The Hedrocel® Revision Cup is a modular acetabular reconstructive system. The Hedrocel® Revision Cup is available in OD sizes from 40 mm to 70 mm. The Hedrocel is compatible with Implex All-Poly Cups and the Hedrocel Replacement Inserts. The system is available with four ID size options (22 mm, 26 mm, 28 mm and 32 mm) and in 0°, and 10° face angles. The Hedrocel® Revision Cup is intended for use with Continuum Hip Bone Screws.

510(k) Summary (continued)

Indications for Use:

The indications for use of the Implex Hedrocel® Revision Cup are as follows :

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Device Technological Characteristics and Comparison to Predicate Device:

A comparison of technical characteristics included in this 510(k) Premarket notification demonstrates that the Hedrocel® Revision Cup is substantially equivalent to commercially available reconstructive devices.

Performance Data:

Testing conducted on the commercially available devices comprised wholly or in part of Hedrocel® supports the fact that device will function as intended.

Conclusion:

The Implex Hedrocel® Revision Cup with Replacement All-Poly Insert is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2000

Mr. John A. Schalago
Manager, Regulatory Affairs
Implex Corporation
80 commerce Drive
Allendale, New Jersey 07401-1600

Re: K001759
Trade Name: Implex Hedrocel® Revision Cup
Regulatory Class: II
Product Code: JDI and LPH
Dated: May 31, 2000
Received: June 9, 2000

Dear Mr. Schalago:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001759

Device Name: Hedrocel® Revision Cup

Indications For Use:

The indications for use of the Implex Hedrocel® Revision Cup are as follows :

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
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- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001759

Prescription Use (Per 21 CFR 801.109) Yes OR... Over-The-Counter Use No

(Optional Format 1-2-96)